Attorney Docket No.: 2870/458 (99.25US)

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Cioca, et al.

Serial No.: 09/838,649 Group Art Unit: 1617

Filed: April 19, 2001 Examiner: Wells, Lauren Q.

For: Stable Antimicrobials in Structured Water

DECLARATION UNDER 37 C.F.R. §1.132

- I, Mirela Ionita-Manzatu, declare and say that:
- 1. I am one of the coinventors in the above-identified patent application.
- 2. I graduated in 1981 from Bucharest University, Department of Physics, located in Bucharest. Romania with a Bachelor in Science degree in Biophysics.
- 3. Since 1994, I have worked in the field of Biocosmetics and Biopharmaceuticals, and I have been employed by Estee Lauder working in this field. Upon the commencement of my employment with Estee Lauder, I was a consultant between 1998 and 1999, and I became a permanent employee, December 1, 1999. Currently, I am a Principal Scientist for the New Venture Department of Research and Development ("R&D") at Estee Lauder.
- 1 am familiar with the Office Action dated April 21, 2004 for the above-identified patent application and the three references cited by the Examiner as rendering the present invention not obvious. I have reviewed the abstract of U.S. Patent Nos. 6,139,855, 6,217,887, and 6,231,837. Specifically, the Examiner asserts that when structured water, having cluster structures, is combined with an antimicrobial agent such as potassium sorbate, the electrostatic charges of potassium sorbate would interact with electrostatic charges of cluster structures of the structured water and achieve the effect of the present invention.
- 5. In my opinion, a solution containing a combination of an antimicrobial agent such as potassium sorbate with structured water differs substantially from a structured water having potassium sorbate <u>integrated within</u> a cluster structure of the structured water. The

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cited references may be considered by the Examiner to teach the addition of potassium sorbate to structured water in solution; but, none of the cited references discloses potassium sorbate integrated within the cluster structure of the structured water. The data presented herein demonstrate that the present invention is not achieved by simple addition of an antimicrobial agent to structured water as disclosed in the cited references.

- 6. In addition to the study described in the present invention, I conducted a comparative study to analyze if the characteristics of a) structured water in combination with an antimicrobial agent in a solution, is different than b) structured water having an antimicrobial agent within its cluster structure. To measure these characteristics an ionic marker is used and detected by fluorescent emission spectral analysis. In particular, terbium (Tb) ions are used as the marker in the study at a concentration of about 3 ppm because they are capable, by spectral analysis, of indicating whether or not they are integrated within the cluster structure of structured water. Three samples were prepared. 1) I water without the Tb marker; 2) I water with 3 ppm Tb marker in the cluster structure of the I water according to the present invention; and 3) I water in solution with 3 ppm Tb marker (i.e., Tb ions are simply added to I water).
- The results of this study sufficiently demonstrate that integrating an antimicrobial agent into the cluster structure of structured water substantially differs from simply adding an antimicrobial agent to a structured water in solution. In particular, samples 1 and 3 exhibit a similar spectral curve due to the peak of each of the curves at about 416 nm, whereas, sample 2 has a peak at about 369 nm. The shift in the peak from about 416 nm to about 369 nm, and the reduction in peak intensity, demonstrates that the electronic configurations in sample 2 are substantially different than samples 1 and 3. It is my opinion that the Tb marker is shielded from fluorescence by its integration within the cluster structure of the structure water in sample 2, and therefore, has a less intense peak than samples 1 and 3. The newly structured water with the Tb marker integrated within the cluster structure is shown by the shift of the peak to a lower wavelength. This difference confirms that structured water having the Tb marker integrated in its cluster structure is not a mere solution, i.e., the Tb marker simply added to the structured water, but rather, a

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different organization of molecules around the marker (i.e., the marker is incorporated within the cluster structure).

- 8. Consistent with the results of this study, it is my opinion, that the present invention of an antimicrobial agent integrated within the cluster structure of structured water is separate and distinct from an antimicrobial agent that is simply added to structured water in solution. Therefore, it is my opinion that the present invention of structured water having an antimicrobial agent integrated within the cluster structure of structured water is substantially different than the simple addition of an antimicrobial agent to structured water described in the cited references. In my opinion, examining all the data as a whole, it is clearly demonstrated that one of ordinary skill in the art would not reasonably expect the addition of an antimicrobial agent to a structured water in solution, as disclosed in the cited references, to achieve a similar effect, and most certainly would not expect an identical effect, as that of the present invention having the antimicrobial agent integrated within the cluster structure of structured water.
- 9. Therefore, in my opinion, the superiority and criticality with respect to the integration of the antimicrobial agent within the cluster structure of structured water as claimed in the above-identified patent application is unobvious to one of ordinary skill in the art, given the disclosures of the cited references in the Office Action of April 21, 2004, and in light of the behavior of structured water having an antimicrobial agent integrated therein as demonstrated by the experimental data presented herein.
- 10. The undersigned declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patents issuing thereon.

Date: <u>07/20/04</u>	Coully
	Mirela Ionita-Manzatu

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